



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Meguid, Michael

Examiner: Hama, Joanne, Ph.D.

Serial No. 10/802,996

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Docket No. RFSUNY 3673

For: ANIMAL WITH SURGICALLY MODIFIED GASTROINTESTINAL TRACT AND METHOD FOR STUDYING OBESITY

DECLARATION UNDER 37 C.F.R. Section 1.132

I, Michael Meguid, M.D., Ph.D. declare and say:

1. I am the Inventor in the above-identified patent application.
2. I am a citizen of the United States of America and I reside at 248 Oarlock Circle, East Syracuse, New York 13057.
3. I am a Professor of Neuroscience and Surgery and Vice Chair of Surgical Research in the Department of Surgery of the Upstate Medical University at the University Hospital, at 750 E. Adams Street, Syracuse, NY 13210. I have held this position at all times relevant to the statements made hereinafter.
4. In the spring of 1999, I alone conceived of the research whose design and findings are the subject matter of the reference *Gastric Bypass Model in the Obese Rat to Study Metabolic Mechanisms of Weight Loss*, (2002, Journal of Surgical Research, 107: 56-63), cited by the Examiner herein as "Xu, et al."
5. In order to obtain funding for this research, I submitted grant applications, in which I am identified as the principal investigator, to the entities whose support is acknowledged in Xu, et al. by the statement:

“This work was supported in part by an educational grant from the Department of Surgery [at the Upstate Medical University], the Hendrick’s Fund, and NIH/DK and by material support to [sic] Ethicon … and Mead Johnson … .”

6a. Exhibit 1 to this declaration is document entitled “SUNY UPSTATE MEDICAL UNIVERSITY COLLEGE FACE SHEET GRANT APPLICATION,” on which the “Title of Proposal” line is followed by the handwritten words, “GASTRIC BYPASS IN OBESITY: GHRELIN-RELATED WEIGHT LOSS.” Exhibit 1 is dated 10/1/01 and bears my signature over the identification “Signature of PI [Principal Investigator].”

6b. On the second page of Exhibit 1, as the principal investigator, I certify that the above-named proposal “DOES NOT DIFFER IN ITS INVOLVEMENT OF VERTEBRATE ANIMAL SUBJECTS FROM THAT WHICH THE CHUA [Committee for the Humane Use of Animals] HAS REVIEWED AND APPROVED.”

7. Exhibit 2 to this declaration is a page from a grant application form of the Public Health Service of the Department of Health and Human Services, (NIH/DK Application) entitled, in box 1, “Gastric Bypass in Obesity: Ghrelin-Related Weight Loss,” requesting funding, inter alia, for the research whose design and findings are the subject matter of Xu, et al. In Box 3A. of Exhibit 2, I am identified as the Principal Investigator/Program Director. To the right of Box 15, my signature appears under the caption “SIGNATURE OF PI [Principal Investigator]/PD [[Program Director] in 3A.”

8a. Exhibit 3 is a letter, dated March 10, 2000, addressed to me, on the letterhead of the Health Science Center (“HSC”) at Syracuse, advising of the approval of my application requesting funding from the HSC, inter alia, for the research whose design

and findings are the subject matter of Xu, et al. In Exhibit 3, reference is made to two accounts: one from the Hendrick's Fund, acknowledged above; and, another from the Research Enhancement Fund for Dr. Chen's salary, Dr. Chen being C. Chen, Ph.D. of the Department of Management Information and Decision of Syracuse University, one of the named co-authors of Xu, et al, and the individual responsible for the analysis of experimental data arising from the research whose design and findings are the subject matter of Xu, et al.

8b. Following the letter of March 10, 2000 is a document entitled "SUNY Health Science Center at Syracuse Intramural Grant Application," in which I am identified as "Principal Investigator."

8c. Following the Intramural Grant Application, is a document entitled "SUNY Health Science Center at Syracuse Application for Research Grant," in which I am identified as "Principal Investigator."

8d. Dr. Chen is described on Page 6 of Exhibit 2 (NIH/DK Application) as a "Consultant."

9. Exhibit 4 is a letter, dated February 27, 2002, addressed to me, on the letterhead of Ethicon Endo-Surgery, Inc., acknowledging "an educational grant of product to *your* research facility." [emphasis supplied]. This letter repeatedly refers to "*your* research project." [emphasis supplied].

10. Exhibit 5 is a letter, dated July 18, 2002, addressed to me, on the letterhead of Mead Johnson, confirming an earlier-made commitment made to me by Mead Johnson to provide nutritional products for use "in *your* research on obesity and gastric bypass rat model." [emphasis supplied]

11. Exhibit 6 is a letter, dated March 30, 2001, on the letterhead of Upstate Medical University's Committee For The Humane Use of Animals ("CHUA"), referring to "CHUA [Protocol] # 713," and advising of its approval, *inter alia*, of the research whose design and findings are the subject matter of Xu, et al. In this letter, I am identified as the Principal Investigator.

12. Exhibit 7 is a document entitled "PROTOCOL FOR THE CARE AND USE OF LABORATORY ANIMALS COMMITTEE FOR THE HUMANE USE OF ANIMALS (CHUA) SUNY UPSTATE MEDICAL UNIVERSITY" in which I am identified as the Principle Investigator in connection with CHUA Protocol #713. The signature page of this document (page 13) bears my signature as the "Principal Investigator."

13. Exhibit 8 is a collection of documents comprising a set of addenda to CHUA Protocol #713, in which I am repeatedly identified as the Principal Investigator.

14a. Exhibit 9 is a document entitled "Addition to Personnel Name List/Qualifications," that is an addendum to CHUA Protocol #713, dated 7/17/2001, in which, as Principal Investigator, I certify that Yuan Xu, a named author of Xu, et al., "will be properly trained prior to beginning work on animals" in connection with the research whose design and findings are the subject matter of Xu, et al.

14b. Additionally, page 5 of Exhibit 2 (NIH/DK Application), states that Yuan Xu is a "Research Associate," who "joined Dr. Meguid's research team in April 2001," and "was specifically *hired* for her skills as an exemplary surgeon with respect to the specific task to develop the 'Gastric Bypass Roux-en-Y rat model.'" [emphasis supplied] Page 5

of Exhibit 2 (NIH/DK Application) also states that “Dr. Xu together with Tomaku Tada, MS, another named author of Xu, et al., will be responsible for collecting and interpreting ... voluminous data ...” Page 6 of Exhibit 2 (NIH/DK Application) further identifies Tomaku Tada, MS as “our only laboratory technician.”

15. Although Kosaku Ohinata is identified as a “co-principal investigator” on page 2 of Exhibit 2 (NIH/DK Application), his role was in fact that of a post-doctoral fellow, working under my supervision, as indicated in Exhibit 10. Exhibit 10 is a document entitled “Addition to Personnel Name List/Qualifications, that is an addendum to CHUA Protocol #713, dated 7/18/01 in which, as Principal Investigator, I certify that Kasaku Ohinata , a named author of Xu, et al., “will be properly trained prior to beginning work on animals” in connection with the research whose design and findings are the subject matter of Xu, et al. Exhibit 10 describes Kasaku Ohinata as a “Post-doctoral Fellow with recently completed PhD.”

16a. Exhibit 11 is a letter, dated September 30, 2001, addressed to me, from Dr. Akio Inui, a named author of Xu, et al., in which he describes his role as a collaborator with me in connection with the research whose design and findings are the subject matter of Xu, et al, as follows:

“In this regard I am happy to collaborate with you through *the exchange of information* and by *providing you with ghrelin antibodies* ... in addition to visiting your laboratory periodically for information exchange sessions.” [emphasis supplied]

16b. Accordingly, Dr. Inui was not a principal investigator, nor did he contribute to the conception, design, or conduct of the research whose design and findings are the subject matter of Xu, et al. Dr. Inui is described on Page 6 of Exhibit 2 (NIH/DK Application as a “Consultant.”

17. R. Quinn, D.V.M., yet another named author of Xu, et al., was a consulting veterinarian from the Department of Laboratory Animal Resources of SUNY Upstate Medical University with respect to the research that is the subject matter of Xu, et al.

18. W. Marx, D.O., yet another named author of Xu, et al., was an occasional clinical consultant with respect to the research that is the subject matter of Xu, et al.

19. As the foregoing Exhibits demonstrate, I am the principal investigator responsible for the design of the research that is the subject matter of Xu, et al. In this capacity, I was exclusively responsible for the conduct of this research, in which other individuals, listed as authors of Xu, et al. participated subject to my supervision.

20. It is customary for me, in my role as a mentor to individuals working under my supervision, such as, for example, Dr. Xu, to promote their careers by placing their names before my own in the listing of authors of a publication.

21. Consequently, the position of the names in the listing of the authors of Xu, et al. does not imply a ranking of relative contributions to authorship. Rather, the inclusion of a name among the listed authors of Xu, et. al is an acknowledgment by me of participation, subject to my supervision, in the research that is the subject matter of Xu, et al.

22. I am advised by my attorney that where, as here, I am the primary author of the a reference cited by the Examiner against my application, the reference may be removed as anticipating under 35 U.S.C. § 102(a) by this Declaration that I am the sole inventor and principal author of the reference, and that other co-authors were merely working under my direction and supervision. Accordingly, in light of the foregoing facts, I respectfully submit that Xu, et al., does not anticipate the present application, and that Claims 1, 2, 4, 5, 7, 8 of this application satisfy the requirements of 35 U.S.C. § 102(a) and are in condition for allowance.

23. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon;

Date: June 17, 2005

Michael Meguid M.D. Ph.D.

Michael M. Meguid, M.D., Ph.D.